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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,947

02/11/2004

Barry M. Freifeld

IB-1842

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7590

03/17/2006

LAWRENCE BERKELEY NATIONAL LABORATORY
ONE CYCLOTRON ROAD, MAIL STOP 90B
UNIVERSITY OF CALIFORNIA
BERKELEY, CA 94720

EXAMINER

KIKNADZE, IRAKLI

ART UNIT

PAPER NUMBER

2882

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,947

Applicant(s)

FREIFELD ET AL.

Examiner

Irakli Kiknadze

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 and 17-28 is/are allowed.
- 6) ☒ Claim(s) 8-16 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/3/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In response to the Office action dated September 21, 2005 the Amendment has been received on November 11/2005.

Claim 29 has been amended.

Claims 1-33 are currently pending in this application.

Response to Arguments

2. Applicant's arguments with respect to claims 8-16 and 29-33 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis (US Patent 4,020,346).

With respect to claims 8-11 and 13, Dennis teaches (Figs. 1 and 4) an imaging device comprising: an x-ray source (20); an X-ray detector (25); and a means for shielding (11) an object (19) to be irradiated by the x-ray source (20) so as to form an image detected by the detector (25); wherein the means for shielding limits external exposure of x-ray radiation produced by the x-ray source (20) (column 2, lines 58-65). Dennis fails to teach that the means for shielding limits external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device; and wherein the means for shielding has a mass of less than 200 kg, less than 14 kg, less than 10 kg or less than 8kg. All X-ray imaging systems produce unintended radiation emissions to operators in proximity to the systems through scatter, transition, and leakage. Various regulatory agencies have determined the energy levels and time durations to which an operator is exposed. In the United States of America, 21 CFR § 1020.40 (c)(1)(i) provides a regulatory standard specifying that: "radiation emitted from the cabinet x-ray system shell not exceed an exposure of 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface". It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sufficient shielding means for shielding external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device of Dennis to meet federal radiation safety requirement allowing to provide the safe working environment protecting the operators from unnecessary x-ray exposure. Further, It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the less shielding material save

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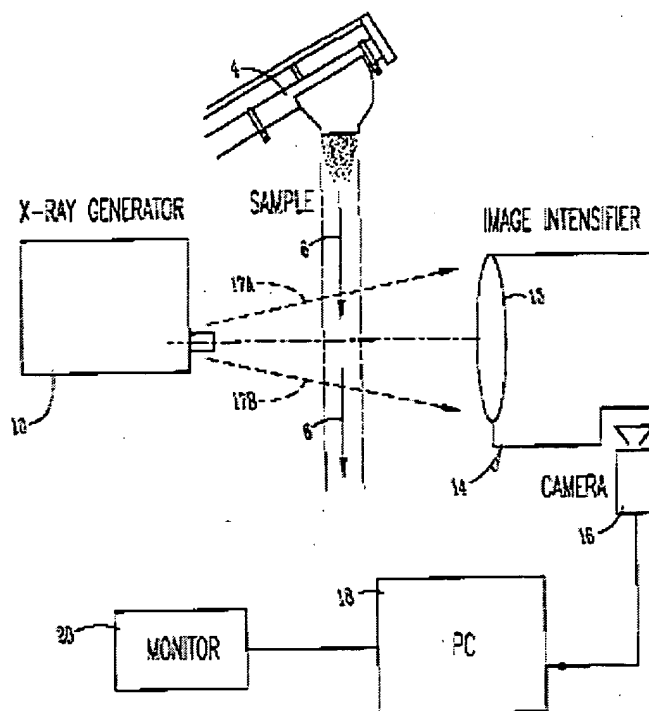
for sufficient shielding in the ranges of: less than 200 kg, less than 14 kg, less than 10 kg or less than 8kg, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in art. As a result, less shielding provides more mobile, portable and compact imaging device.

With respect to claim 12, Dennis teaches that the means for shielding (24) is disposed between the x-ray source (20) and the detector (25) (Fig.4; column 3, lines 9-19).

With respect to claims 14-16, Dennis teaches claimed invention except that the X-ray has an energy selected from the group comprising: 10-130 kV, 20-130 kV, and 70-80 kV or has a wavelength between about 10^{-5} to 10^3 Å or a wavelength between about $(10^{-5} - 10^3) \times 10$ meters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the X-ray having an energy selected from the group comprising: 10-130 kV, 20-130 kV, and 70-80 kV or has a wavelength between about 10^{-5} to 10^3 Å or a wavelength between about $(10^{-5} - 10^3) \times 10$ meters it the device of Dennis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

5. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (US Patent 6,526,120 B1).

With respect to claim 29, Heesch teaches a portable imaging device for imaging a sample (6) (column 6, lines 27-33) contained within a shielded volume (a pipe or tube; column 6, lines 53 and 55) comprising (Fig.2):



- a) means for generating penetrative photons (10) for imaging a sample (6);
- b) means for detecting penetrative photons (an image intensifier; 14) transmitted through the sample (6) and creating an image; and
- c) means for shielding the penetrative photons (Fig. 2; column 6, lines 45-55).

Gray fails to teach that the means for shielding limits external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device. All X-ray imaging systems produce unintended radiation emissions to operators in proximity to the systems through scatter, transition, and leakage. Various regulatory agencies have determined the energy levels and time

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durations to which an operator is exposed. In the United States of America, 21 CFR § 1020.40 (c)(1)(i) provides a regulatory standard specifying that: "radiation emitted from the cabinet x-ray system shell not exceed an exposure of 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface". It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sufficient shielding means for shielding external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device of Gray to meet federal radiation safety requirement allowing to provide the safe working environment protecting the operators from unnecessary x-ray exposure.

6. Claims 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dykster et al. (US Patent 5,712,893).

With respect to claim 29, Dykster teaches an imaging device (10) for imaging a sample (55) (Fig.1; column 4, lines 39 and 40) contained within a shielded volume (20; 22) comprising:

- a) means for generating penetrative photons (44) for imaging a sample (55);
- b) means for detecting penetrative photons (an image intensifier; 46) transmitted through the sample (55) and creating an image; and
- c) means for shielding the penetrative photons (16, 18, 22, 24 and 26) comprising a layered or laminated material comprising lead (Fig. 1; column 3, lines 54-57).

Dykster fails to teach that the means for shielding limits external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device. All X-ray imaging systems produce unintended radiation emissions to operators in proximity to the systems through scatter, transition, and leakage. Various regulatory agencies have determined the energy levels and time durations to which an operator is exposed. In the United States of America, 21 CFR § 1020.40 (c)(1)(i) provides a regulatory standard specifying that: "radiation emitted from the cabinet x-ray system shell not exceed an exposure of 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface". It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sufficient shielding means for shielding external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device of Dykster to meet federal radiation safety requirement allowing to provide the safe working environment protecting the operators from unnecessary x-ray exposure.

With respect to claim 31, Dykster teaches means (12) for mechanically protecting personnel (the device 10 is generally housed within a housing or inclosure) from movements of a rotating table (50) of the imaging device (10) (column 3, lines 33-36 and column 4, lines 32-35).

With respect to claims 32 and 33, Dykster teaches a circular rotating table (50) for translating and rotating the sample (55) relative to the imaging device (10) (column 4, lines 32-40).

7. Claims 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dykster et al. (US Patent 5,712,893) as applied to claim 29 above, and further in view of Zhang et al. (US Patent 6,935,779 B2).

With respect to claim 30, Dykster teaches claimed invention except for means for telescoping the generating means closer and further away from the detecting means. Zhang teaches a radiographic imaging apparatus comprising means (35) for telescoping the generating means (12) closer and further away from the detecting means (22) (Fig. 1; column 3, lines 65 – column 4, line 6). This arrangement would provide user with capabilities to precisely align generating means (12) relative to the detecting means (22). It would have been obvious to one of ordinary skill in art at the time the invention was made to use a telescopic arm (35) movement as suggested by Zhang in the device of Dykster, since such a modification would provide user with capabilities to move the generating means closer and further away from the detecting means to provide the precise alignment of the imaging system components.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dykster et al. (US Patent 5,712,893) as applied to claim 29 above, and further in view of Levine et al. (US Patent 6,389,101 B1).

With respect to claim 33, Dykster teaches claimed invention except translating and rotating the sample relative to the imaging device for generating three-dimensional representation of the sample. Levine teaches translating and rotating the sample

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relative to the imaging device and generating three-dimensional representation of the sample (column 6, lines 17-27; column 9, lines 18-23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use translating and rotating of the sample relative to the imaging device and generating three-dimensional images as suggested by Levine in the device and method of Dykster, since such modification would allow user generating three-dimensional images for enhanced visual interpretation of the sample.

Allowable subject matter

9. With respect to claims 1-7, prior art fails to teach or make obvious an X-ray imaging device for imaging a sample, wherein the sample is within an X-ray shielded volume comprising: a first volume shield defining an elongated generally convex receptacle for receiving a first portion of the sample and having therein a transverse elongated shielding portion slidably coupled to a source beam shield; and a second volume shield defining an elongated generally convex receptacle for receiving a second portion of the sample, and having therein a transverse elongated shielding portion slidably coupled to an exit shield as claimed in combination with all elements of claim 1.

10. With respect to claims 17-28 prior art fails to teach or make obvious an X-ray imaging device for imaging a sample contained within an X-ray shielded volume comprising: an X-ray shielded volume comprising: a core volume shielded by a left

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volume shield and a right volume shield separably connected so as to permit insertion and removal of a sample, the core volume having a top opening and a bottom opening, a shielded telescoping sleeve permitting elongation of a beam path volume as claimed in combination with all elements of claims 17 or 28 as applied.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irakli Kiknadze whose telephone number is 571-272-2493. The examiner can normally be reached on 9:00-5:30.

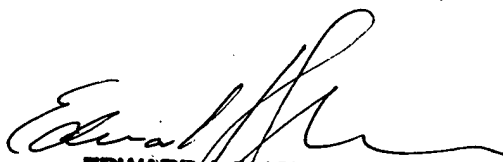
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on 571-272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 9, 2006
Irakli Kiknadze

IK


EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER